



## THE ATTORNEY GENERAL OF TEXAS

October 8, 1986

**JIM MATTOX**  
**ATTORNEY GENERAL**

Jerry Hodge, R.Ph.  
President  
Texas State Board of Pharmacy  
211 East 7th Street, Suite 1121  
Austin, Texas 78701

Opinion No. JM-555

Re: Whether the State Board of  
Pharmacy may license and regu-  
late out-of-state mail-order  
pharmacies

Dear Dr. Hodge:

On behalf of the Texas State Board of Pharmacy you ask the following questions:

1. Whether sections 18 and 29 of article 4542a-1, V.T.C.S., authorize the board to license out-of-state pharmacies or pharmacists which solicit mail-order sales of prescriptions from Texas residents.

2. Whether requiring licensing by the board of out-of-state pharmacies or pharmacists, whether pursuant to a specific statute or based on an implied legislative mandate, establishes an unconstitutional burden on interstate commerce.

3. If it is assumed that out-of-state pharmacies and pharmacists may dispense prescriptions by mail to Texas residents without being licensed by the board, [whether] the pharmacies or pharmacists [must] nevertheless comply with other provisions of article 4542a-1, V.T.C.S. (Texas Pharmacy Act), article 4476-15, V.T.C.S. (Texas Controlled Substances Act), and article 4476-14, V.T.C.S. (Texas Dangerous Drugs Act), regarding the dispensing of prescriptions drugs.

As a fundamental rule, administrative agencies have only those powers granted by statute and those powers necessarily implied from the statutory authority conferred or duties imposed. City of Sherman v. Public Utility Commission, 643 S.W.2d 681, 686 (Tex. 1983); see also State ex rel. Grimes County Taxpayers Association v. Texas Municipal Power Agency, 565 S.W.2d 258 (Tex. Civ. App. - Houston [1st Dist.] 1978, no writ). You premise your first question specifically

on sections 18 and 29 of the Texas Pharmacy Act, article 4542a-1, V.T.C.S. You also cite sections 17 and 19 of the act in your request letter.

Section 17 details the board's responsibilities, in part, as follows:

(a) The board is responsible for the regulation of the practice of pharmacy in this state, including the following:

(1) the licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy and the licensing of pharmacies under this Act;

(2) the renewal of licenses to engage in the practice of pharmacy and licenses to operate pharmacies;

. . . . .

(4) the enforcement of those provisions of this Act relating to the conduct or competence of pharmacists practicing in this state and the conduct of pharmacies operating in this state and the suspension, revocation, fining, reprimanding, cancellation, or restriction of licenses to engage in the practice of pharmacy or to operate a pharmacy;

. . . . .

(6) the enforcement of this Act and any rules adopted under this Act.

(b) The board has the following responsibilities relating to the practice of pharmacy and to prescription drugs and devices used in this state in the diagnosis, mitigation, and treatment or prevention of injury, illness, and disease:

(1) regulation of the delivery or distribution of prescription drugs and devices, including the right to seize, after notice and hearing, any prescription drugs or devices posing a hazard to the public health and welfare, but the board may not regulate: [certain manufacturing and wholesale exceptions];

(2) specification of minimum standards for professional environment, technical equipment, and security in the prescription dispensing area; and

(3) specification of minimum standards for drug storage, maintenance of prescription drug records, and procedures for the delivery, dispensing in a suitable container appropriately labeled, or providing of prescription drugs or devices within the practice of pharmacy. (Emphasis added).

Section 19 states, in part, that

(a) A person may not dispense or distribute prescription drugs unless he is a licensed pharmacist or is authorized by this Act to dispense or distribute prescription drugs. (Emphasis added).

Section 29 provides that

(a) A pharmacy shall annually register with the board.

. . . . .

(d) The board shall establish by rule the standards that each pharmacy and its employees or personnel involved in the practice of pharmacy shall meet to qualify for the licensing or re-licensing as a pharmacy in each classification.

. . . . .

(f) The board shall have the authority to inspect facilities licensed under this Act for compliance with this Act.

Section 18 adds to section 29(f) by providing for extensive administrative inspections of the physical facilities of pharmacies under the board's jurisdiction.

In light of these provisions, the context of your first question requires consideration of regulation both of "the practice of pharmacy" and of "pharmacies." You do not present any specific administrative rules which explain how the board plans to apply all of these provisions to out-of-state mail-order pharmacies. The legislature intended to grant the board statutory authority, under sections 17 and 19, to regulate the practice of pharmacy by out-of-state

pharmacists and pharmacies only to the extent they actually engage in business within the state of Texas. Although this may include annual registration of pharmacies under section 29(a), the legislature could not have intended the board to physically inspect, pursuant to sections 18 and 29(f), facilities located in other states. Thus, this statute permits the board to require that persons who practice pharmacy in Texas be licensed; it does not allow the board to license pharmacies that are located outside of Texas.

Section 17 authorizes the board to regulate the "practice of pharmacy in this state." Section 19 authorizes the board to prohibit persons from engaging unlawfully in the "practice of pharmacy." The "practice of pharmacy" is defined in section 5 of article 4542a-1 as follows:

(29) 'Practice of pharmacy' means interpreting and evaluating prescription or medication orders, dispensing and labeling drugs or devices, selecting drugs and reviewing drug utilization, storing prescription drugs and devices and maintaining prescription drug records in a pharmacy, advising or consulting when necessary or required by law about therapeutic value, content, hazard, or use of drugs or devices, or offering or performing the services and transactions necessary to operate a pharmacy. (Emphasis added).

Sections 17 and 19 also provide direct authority to regulate the dispensing, distributing, and delivering of prescription drugs. See §§17(b)(1)-(3); 19(a). These terms are defined in section 5 as follows:

(14) 'Deliver' or 'delivery' means the actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

. . . .

(16) 'Dispense' means preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(17) 'Distribute' means the delivery of a prescription drug or device other than by administering or dispensing. (Emphasis added).

Out-of-state mail-order pharmacists or pharmacies which fill prescriptions for Texas residents clearly deliver, dispense, or distribute those prescriptions in Texas. Consequently, the legislature granted authority in sections 17 and 19 of article 4542a-1 to regulate mail-order sales or transfers of prescription drugs from out-of-state pharmacists or pharmacies to persons within Texas with regard to the aspects of such practice that may directly affect users residing in Texas. See also V.T.C.S. art. 4476-14, §2(b); art. 4476-15, §1.02(8)-(13).

Your second question is whether such regulation would create an unconstitutional burden on interstate commerce. Because you do not present specific administrative rules detailing exactly which aspects of sections 17 and 19 will be applied to out-of-state pharmacies and pharmacists and how those provisions will be applied, this opinion can provide only the general principles of law established in similar cases under the Commerce Clause of the United States Constitution.

The basic criteria for determining the validity of state statutes and actions which affect interstate commerce are set forth in Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970), as follows:

Where the statute regulates evenhandedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities. (Citation omitted).

Authorities in several jurisdictions across the country have considered the constitutionality of different statutory schemes which regulate out-of-state mail-order pharmacists or pharmacies with varying results. Some upheld the constitutionality of their statutes under the Commerce Clause. See, e.g., Pharmaceutical Manufacturers Association v. New Mexico Board of Pharmacy, 525 P.2d 931 (N.M. Ct. App. 1974); Wisconsin Attorney General Opinion No. 33-83 (August 23, 1983); See also 61 Op. Cal. Att'y Gen. 192 (No. CV 76-212, CV 77-236; May 2, 1978). Others have not. See, e.g., Iowa v. Rasmussen, 213 N.W.2d 661 (Iowa 1973); Nebraska Attorney General Opinion No. 57 (April 4, 1985); Ohio Attorney General Opinion No. 82-032 (May 4, 1982). All of these opinions agree, however, that regulation of prescription drugs meets the first part of the constitutional test

under the Commerce Clause -- that the regulation must effect a legitimate local interest.

Article 4542a-1, in section 2, recognizes that the practice of pharmacy in this state affects the health, safety, and welfare of the public. The overall purpose of the act is to protect the consumers of prescription drugs. The State Board of Pharmacy also has regulatory duties with regard to controlling drug abuse and misuse under the Texas Controlled Substances Act, article 4476-15, V.T.C.S., and the Texas Dangerous Drugs Act, article 4476-14, V.T.C.S. The regulation of the delivery, distribution, and dispensing of prescription drugs is well within the traditional definition of a state's police power. See Head v. New Mexico Board of Examiners in Optometry, 374 U.S. 424, (1963); Pharmaceutical Manufacturers Association v. New Mexico Board of Pharmacy, 525 P.2d at 931.

In Pike v. Bruce Church, Inc., 397 U.S. at 142, the Court stated that regulation must be evenhanded. The Texas Pharmacy Act is, on its face, even-handed. Under the Commerce Clause, application of the state statute must not discriminate against nonresidents engaged in interstate commerce. See Pike v. Bruce Church, *supra*; Hunt v. Washington Apple Advertising Commission, 432 U.S. 333 (1977). Because article 4542a-1 applies to both in-state and out-of-state pharmacists and pharmacies, and does not authorize regulations for out-of-state pharmacists and pharmacies which do not apply to those in Texas, it is not *per se* unconstitutional. See Iowa v. Rasmussen, 213 N.W.2d at 667; Nebraska Attorney General Opinion No. 57, at 4; Ohio Attorney General Opinion No. 82-032, at 5; Wisconsin Attorney General Opinion No. 33-83, at 4.

Nevertheless, even if state regulation of mail-order pharmacists and pharmacies serves a legitimate public interest and is applied evenhandedly, under the test set forth in Pike v. Bruce Church, the burden imposed on interstate commerce by regulation must not outweigh the benefits derived. As quoted above, the court in Pike v. Bruce Church stated that the question is one of degree, depending on the nature of the local interest involved and on whether the interest could be promoted in a less burdensome way. 397 U.S. at 142. The extent of the burden imposed is the analytical point on which legal authorities diverge.

The court in Pharmaceutical Manufacturers Association v. New Mexico Board of Pharmacy characterized the regulations and the licensing fee imposed by the New Mexico statutes as a small burden in relation to the state's interest in drug control. 525 P.2d at 935. The regulations in question were similar to those at issue here insofar as they dealt with regulation of safe storage and labeling of drugs and with the registration or licensing of pharmacists. Similarly, the Wisconsin Attorney General determined that the primary purpose and effect of such regulation is to protect the public.

Because the effect on interstate commerce was merely incidental to this purpose, no undue burden on interstate commerce was found to exist. Opinion No. 33-83, at 4; see also 61 Op. Cal. Att'y Gen. 192.

In contrast, the court in Iowa v. Rasmussen, supra, struck down state regulations which, in practical effect, prohibited Iowa pharmacists from filling prescriptions written by nonresident physicians who were not registered by Iowa authorities. 213 N.W.2d at 663. Clearly, the issue involved here differs. Moreover, the court in Rasmussen declined to rule on whether the local interest involved outweighed the burden imposed, relying instead on a preemption argument. The court cited Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440 (1960), for the proposition that, under the Commerce Clause, state regulation must not disrupt "uniformity" in interstate commerce. 213 N.W.2d at 667. The Rasmussen court concluded that state regulation would prevent uniformity in administering federal registration provisions enacted to control drug trafficking. See also Ohio Attorney General Opinion No. 82-032, at 6.

The court's conclusion with regard to preemption, however, is no longer persuasive. Congress did not intend to preempt the field of drug abuse control:

No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together. (Emphasis added).

21 U.S.C. §903 (1982). The Texas Pharmacy Act parallels, rather than conflicts with the federal statute. See, e.g., art. 4542a-1, §§5 (10)-(12); 6; see also arts. 4476-14, 4476-15.

The Nebraska Attorney General stated that having to meet the licensing requirements of a number of states would impose a substantial burden on the pharmacies' ability to engage in interstate commerce. Opinion No. 57, pp. 4-5. The opinion stated that

[i]n such an instance, the pharmacy involved would be subject to multiple licensing procedures, including duplicative registrations, records requirements, and labeling requirements.

Id. The regulations were also deemed to be unnecessarily duplicative because they operated parallel to the federal statutes. The added

burden of complying with a duplicative statute regarding the practice of pharmacy, with the "burden" lying primarily in registration and in additional reporting, labeling, and record keeping functions, is not sufficient to outweigh the state's interest in the control of potentially dangerous drugs. If the pharmacy has already created records, it should not be a tremendous "burden" to provide extra copies of those records.

This burden is substantially less onerous than the regulations which have been held unconstitutional by the Supreme Court under the Commerce Clause. For example, in Pike v. Bruce Church, the Supreme Court struck down a statute which stated a primary purpose of promoting and preserving the reputation of Arizona cantaloupe growers by prohibiting deceptive packaging and requiring a certain type of packaging prior to shipment out of state. The parties stipulated that the practical effect of the statute was to compel the company in question to build a packing facility in Arizona. The Court recognized that burdens on commerce which require business operations to be performed in the home state that could more efficiently be performed elsewhere must be viewed with particular suspicion. 397 U.S. at 145; see also Hunt v. Washington Apple Advertising Commission, 432 U.S. 333 (1977); Dean Milk Company v. City of Madison, Wisconsin, 340 U.S. 349 (1951). The Court has upheld a number of ordinances and statutes with burdens of the relatively minor magnitude involved here. See, e.g., Exxon Corporation v. Governor of Maryland, 437 U.S. 117 (1978); Breard v. Alexandria, 341 U.S. 622 (1951); Hartford Accident and Indemnity Co. v. Illinois, 298 U.S. 155 (1936); Asbell v. Kansas, 209 U.S. 251 (1908).

The argument has also been advanced that if a statute is, on its face, for the protection of local economic benefit, then such a statute is per se unconstitutional as an undue burden on interstate commerce. See Iowa v. Rasmussen, 213 N.W.2d at 666-67 (citing Pike v. Bruce Church, 397 U.S. at 145). As indicated, however, article 4542a-1 applies to both in-state and out-of-state pharmacists and pharmacies with regard to the practice of pharmacy; it does not protect local pharmacists.

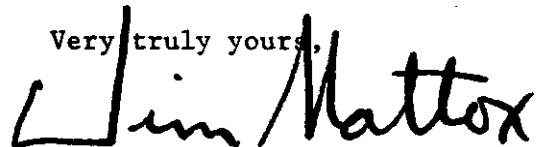
The purpose of the act is to protect the drug-consuming public; thus the burden on interstate commerce is merely incidental and is outweighed by Texas' interest in controlling the dispensing, distribution, and delivery of prescription drugs. Because you do not present any specific administrative rules which explain how the board plans to regulate out-of-state mail-order pharmacies and pharmacists, we can only state that regulation by the board of out-of-state pharmacies and pharmacists is not per se unconstitutional under the Commerce Clause. We emphasize that the law requires the least burdensome regulation which will effect the state's objectives. The numerous cases cited in this opinion should provide guidance as to what sorts of regulation have been held to be overly burdensome.

In light of this response to your first two questions, this opinion does not address your third question.

S U M M A R Y

The Texas State Board of Pharmacy may regulate out-of-state mail-order pharmacists only to the extent that they actually engage in the practice of pharmacy or dispense, deliver, or distribute prescription drugs within the state of Texas. Such regulation is not per se unconstitutional under the Commerce Clause of the United States Constitution.

Very truly yours,

A handwritten signature in black ink that reads "Jim Mattox". The signature is written in a cursive, slightly slanted style.

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